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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,899	01/09/2001	Franciscus Antonius, M. Redegeld	4692US	1305

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EXAMINER	
HUYNH, PHUONG N	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/756,899	REDEGELD ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *1,10,33 and 34*.

   Claim(s) withdrawn from consideration: *None*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because:

Claim 10 stands rejected under 35 U.S.C. 112, first paragraph for the same reasons of record.
Applicants' arguments filed 11/5/04 have been fully considered but are not found persuasive. Applicnant's position is that Examples 2, 3 and 4 are working examples of in vivo experiments performed on sensitized mice. The disclosed examples teach a person of ordinary skill in the art that the claimed composition inhibits binding of free IgLC to mast cells. Applicants have disclosed activity that coupled with the aknowledge of how to use the activity, enables a person of ordinary skill in the art to make and use the claimed invention without undue experimentation. However, the claim encompass a pharmaceutical compositon consisting of a peptide consisting of an amino acid sequence of SEQ ID NO: 1 for treating any disease (claim 10).

Claims 1, 10, and 33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al (of record, J Clin Invest 99(4): 732-36, 1997; PTO 1449) for the same reasons of record.
Applicants' arguments filed 11/5/04 have been fully considered but are not found persuasive. Applicnant's position is that Huang et al does not disclose a pharmaceutical composition consisting of a petpide sequence AHWSGHCCL an a pharmaceutically acceptable carrier or diluent. Huang et al discloses the peptide of SEQ ID NO: 1 together with immunoglobulin light chain (LC) and LC is not the peptide of SEQ ID NO: 1.
In contrast to applicant's assertion that Huang discloses only peptide of SEQ ID NO: 1 together with immunoglobulin light chain (LC), Huang et al teaches a pharmaceutical composition consisting of a synthetic peptide AHWSGHCCL which is 100% identical to the claimed SEQ ID NO: 1 and a pharmaceutical carrier such as 7.25 mM buffer (See Table 1, page 733, col. 1, binding analysis and peptide blocking studies, in particular). The reference further teaches that the reference peptide is synthesized at the protein core facility of the University of Alabama and kept lyophilized at –20C until use (See page 732, col. 2, Protein and peptide preparations, in particular). Just prior to lyophilization and after synthesis, the reference peptide is in buffer. The liquid associated with the reference peptide prior to lyophilization is considered a form of pharmaceutical carrier. Further, the reference peptide is diluted in buffer just prior to adding to the wells of microplates coated with LCs (See page legend of figure 2, in particular). The reference peptide in buffer just prior to adding to the immunoglobulin light chain meets the claimed limitations.

Claims 1, 10, 33 and 34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al (J Clin Invest 99(4): 732-36, 1997; PTO 1449) in view Gennaro et al in Remington's Pharmaceutical Sciences, eighteenth edition, 1990, pages 1300-1329; PTO 892) for the same reasons of record.
Applicants' arguments filed 11/5/04 have been fully considered but are not found persuasive. Applicnant's position is that Huang et al provides no motivation to use the peptide as a pharmaceutical comosition. In the absence of a teaching by Huang et al that the peptide would be a useful pharmaceutical, motivation to combine the references can only be provided by using impermissible hindsight, which is only provided by the present application.
In contrast to applicant's assertion that Huang et al provides no motivation to make or use the peptide as a pharmaceutical composition, Huang et al teach that the reference peptide is useful for inhibiting the binding of the of immunoglobulin light chain to the THP (See Table 1 mic, IC50 mM, in particular). Further, It is noted that none of the claims are drawn to a method of using the claimed composition. Finally, Huang et al teach the same peptide in the claimed composition. A product is a product, irrespective of its intended use.

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